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REMARKS

Claims 1-23 were examined. Claims 1, 3, 7, 9, 14, 16, 18 and 23 are amended. Claims 12 and 13 are canceled. Claims 1-11 and 14-23 remain in the Application.

The Patent Office objects to the information disclosure statement filed October 25, 2001. The Patent Office also objects to claim 23 and the priority designation of the specification. With respect to rejections, the Patent Office rejects claims 1-23 under 35 U.S.C. §112, first paragraph, and §102(e) and/or §103(a). Finally, the Patent Office rejects claims 1-23 under the judicially created doctrine of obviousness-type double patenting. Reconsideration of the pending claims is requested in view of the above amendments and the following remarks.

A. Information Disclosure Statement

The Patent Office requests a clean copy of Information Disclosure Statement. Applicants include herewith a form PTO/SB/08 listing the references previously considered by the Patent Office in connection with application Serial No. 09/365,156. Applicants respectfully request that the Patent Office consider the Information Disclosure Statement submitted herewith.

B. Objection to Claim 23

The Patent Office objects to claim 23 and request that "comprises" be "further comprises." Applicants amend claim 23 per the suggestion of the Patent Office and respectfully request withdrawal of the objection.

C. Priority

The Patent Office believes Applicants have not complied with one or more conditions under 35 U.S.C. §120 to receive a benefit of an earlier filing date (the filing date of U.S. patent application Serial No. 09/365,156).

Applicants designated the Application as a continuation of co-pending application Serial No. 09/365,156 ("the Parent Application"), by including a reference to the Parent Application in paragraph **[0001]**. The inventors identified on the application are the same as on the Parent Application.

The application was designated as a continuation, because Applicants believe that the subject matter of each of the claims (claims 1-23) was disclosed in accordance with the requirements of 35 U.S.C. §112, first paragraph. For example, a beverage composition including calcium, acid and

inulin was described in the Parent Application as was a solid composition, such as a paste or a bar of similar components. Regarding specific examples, the Parent Application described several beverage compositions each of which included among other components, calcium, magnesium, acid, inulin, and isoflavones. The examples (beverage or components) should not be interpreted as limiting what was disclosed under 35 U.S.C. §112, first paragraph. The continuation application added further examples, particularly of solid compositions (e.g., cookies), as well as further examples of beverage compositions that, as noted previously, had previously been disclosed, including with other examples, in the parent application. Applicants also described various types of acids and amounts of acid relative to calcium through examples in both the Parent Application and the Application.

D. 35 U.S.C. §112, First Paragraph: Rejection of Claims 1-23

The Patent Office rejects claims 1-23 under 35 U.S.C. §112, first paragraph. According to the Patent Office, the specification is not enabling for all acids or solubilizers.

1. Acid/Acidifier

With respect to a suitable acid, independent claim 1 describes a beverage composition suitable for human consumption comprising effective amounts of, among other components, an acid. The components are together in a soluble composition. Based on the claim language and the specification, a suitable acid is one that renders the beverage composition (1) soluble, and (2) suitable for human consumption. Applicants believe one of skill in the art can select an acid suitable for human consumption that in the presence of the other components, would render a soluble composition, based on the teachings of the specification, without undue experimentation. Although, Applicants believe it is unnecessary to further amend independent claim 1, Applicants do amend to recite "an organic acid" in an effort to expedite prosecution.

Independent claim 7 also recites a method including administering a beverage composition suitable for human consumption including, among other solubilized components, an acid. Thus, similar to independent claim 1, Applicants believe a person skilled in the art would be able to select an appropriate acid, given the teachings in the specification, to be used in a beverage composition suitable for human consumption and allowing the compounds to be solubilized. Applicants, however, amend claim 7 to recite an organic acid for the purpose of expediting prosecution.

Independent claim 14 relates to a composition that is suitable for human consumption including, among other components, an acidifier. Like the claims noted above, an acidifier must be suitable for human consumption. Applicants believe one of skill in the art would, based on the

teachings of the specification, be able to select an acidifier for the composition that is suitable for human consumption.

2. Stabilizing Agent

With respect to the stabilizing agent, claim 3 which depends from independent claim 1, recites a stabilizing agent comprising maltol and one of carrageenan and maltodextrin and a xanthan gum. Applicants believe the description of a stabilizing agent is completely supported by the specification and no further amendment is needed for one of skill in the art to practice the invention described in the claim. Applicants assume the Patent Office's rejection arises from a typographical error in the specification at paragraph [0025]. Applicants have corrected the typographical error and believe a person of skill in the art would, based on the teachings of the specification, be able to select a suitable stabilizing agent for the beverage composition administered in the method of claim 3.

Claim 9 which depends from independent claim 7 also describes administering a beverage composition that includes a stabilizing agent. For the reasons stated with respect to claim 3, Applicants believe that one of skill in the art would, given the teachings to the Specification, be able to select an appropriate stabilizing agent.

Claim 17, which depends from claim 14, describes a composition which includes a stabilizing agent. Applicants believe, for the reasons stated above with respect to claim 3, that one of skill in the art would, given the teachings of the Specification be able to select an appropriate stabilizing agent for a composition described.

Applicants respectfully request that the Patent Office withdraw the rejection to claims 1-23 under 35 U.S.C. §112, first paragraph.

E. 35 U.S.C. §102(e)/§103(a): Rejection of Claims 1-23

The Patent Office rejects claims 14-16, 20 and 22 under 35 U.S.C. §102(e) as anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,051,260 issued to Liska et al. (Liska). The Patent Office directs Applicants' attention to columns 10 and 11 and claims 7-15 of Liska where a composition that is mixed in water contains inulin, fructooligosaccharides, calcium panthothenate, ascorbic acid, vitamin E, calcium citrate, magnesium citrate, potassium phosphate, vitamin D3 and vitamin K.

Independent claim 14 relates to a composition, including a calcium compound, a magnesium compound, inulin, and an acidifier in an amount up to the equivalent amount of a calcium of the

calcium compound. Claim 14 is not anticipated by nor a prima facie obvious of Liska, because Liska fails to describe an acidifier in an amount up to the equivalent amount of a calcium of the calcium compound. Liska discloses a source of pantothenic acid (not pantothenic acid) and folic acid. Neither of pantothenic acid (Vitamin B complex), folic acid (Vitamin B) are described as acidifiers. Further, there is no teaching or motivation in Liska to add an acidifier in the composition of Liska.

Applicants respectfully request the Patent Office withdraw the rejection of independent claim 14 under 35 U.S.C. §102(e) or §103(a). Claims 15-16, 20 and 22 depend from claim 14 and therefore contain all the limitations of that claim. For at least the reasons noted above with respect to claim 14, claims 15-16, 20 and 22 are not anticipated by or obvious over Liska.

Applicants respectfully request the Patent Office withdraw the rejection to claims 15-16, 20 and 22 under 35 U.S.C. §102(e) or §103(a).

F. 35 U.S.C. §103(a): Rejection of Claims 1-23

The Patent Office rejects claims 1-23 as obvious over Liska in view of U.S. Patent No. 5,900,255 issued to Ohta et al. (Ohta) in view of European Patent Application No. WO99/07392 of Otsuka Pharmaceutical Co., Ltd. (Otsuka), "Improvement of Calcium Absorption" by Orafti (Orafti), U.S. Patent No. 6,171,633 issued to Dulebohn et al. (Dulebohn), and U.S. Patent No. 6,150,399 issued to Patel et al. (Patel).

Liska is cited as before for teaching a composition that can be mixed in water or fruit juice containing inulin, fructooligosaccharides, calcium and magnesium. As noted above, Liska does not describe a relationship between an acid or acidifier and the calcium component or the solubility of a beverage composition.

Ohta describes a composition comprising calcium, magnesium, and fructooligosaccharides. The composition can be in a liquid form, however, no detail is given as to whether such material would be soluble in the liquid. Ohta also does not describe an acid or acidifier in relation to a beverage a calcium component. The examples given for application include biscuits (Example 2), chocolates (Example 3), and candies (Example 4).

Otsuka describes a daidzein-containing and isoflavone-containing composition and mentions the suitability in treating osteoporosis at page 9, line 43. Otsuka also mentions that a form of the composition includes drinks. Page 10, line 28. In Example 7, a drink is described with "water-soluble soya isoflavone material." Page 13, lines 16-34. The drink does not contain

calcium, magnesium, or inulin.

Orafti describes the experimental observation of calcium and magnesium by inulin-type fructons. Orafti does not describe a solubilized beverage of such components or a relationship between an acid or acidifier and a calcium component.

Dulebohn describes a milk/juice combination with a gum-based stabilizer and a composition including an amino acid, an acid, a metal and stabilize the composition for up to one year. One example of the stabilizing composition is 4.69 moles MgO; 2.72 moles malic acid; and 3.41 moles citric acid. From these examples, the amount of acid is 6.13 moles. There is no example where a calcium composition is present in that amount.

Patel describes a soy protein/isoflavone nutritional composition. Patel uses a carbohydrate system including maltodextrin, corn syrup and sucrose to optimize the mouth feel of the product. Carrageenans may also be included to improve the suspension of insoluble minerals, product stability and mouth feel. Patel does not describe a relationship between a calcium component and an acid component. The liquid beverage also does not, from Applicants' understanding, appear to be a solubilized beverage.

Independent claim 1 is prima facie not obvious over the cited references, because the cited references fail to describe a method including administering a beverage composition of solubilized components and a pH modifying acid in the beverage is present in an amount of up to the equivalent amount of a calcium in the beverage composition. Liska, Ohta and Otsuka each describes drinks with collectively, calcium, inulin, and fructooligosaccharides, but do not describe the components collectively solubilized in a drink. Otsuka describes water soluble soya, but no calcium or inulin. Dulebohn and Patel describe beverage compositions, but not a solubilized composition.

From the cited references, there is no motivation for the method described by independent claim 1. Representatively, it is generally known that calcium is difficult to solubilize. See U.S. Patent No. 5,401,524 issued to Burkes et al. (Burkes) and U.S. Patent No. 5,389,387 issued to Zuniga et al. (Zuniga). Therefore, it cannot be assumed that the references cited by the Patent Office will produce a solubilized component absent, for example, some teaching of how solubilization is achieved, such as the relationship of the acid component.

For the above stated reasons, independent claim 1 is not obvious over the cited references. Claims 2-6 depend from claim and therefore contain all the limitations of that claim. For at least stated with respect to claim 1, claims 2-6 are not obvious over the cited references.

Independent claim 7 relates to a method including administering a beverage composition having solubilized components of calcium, magnesium, an acid, and a fructooligosaccharides. Claim 7 is prima facie not obvious over the cited references because the references fail to describe a composition of solubilized component or an acid present in an amount up to the equivalent amount of a calcium of the calcium compound. For the reasons stated with respect to independent claim 1, there is likewise no motivation from the cited references for administering a beverage composition of solubilized compounds as claimed.

For the above stated reasons, independent claim 7 is not obvious over the cited references. Claims 8-11 depend from claim 7 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 7, claims 8-11 are not obvious over the cited references.

Independent claim 14 relates to a composition including calcium, magnesium, inulin and an acidifier in an amount up to the equivalent amount of a calcium. The composition, when combined in solution, the composition is translucent. Claim 14 is prima facie not obvious over the cited references, because the cited references fail to disclose a composition including an acidifier in an amount up to the equivalent amount of a calcium of the calcium compound in the composition, or a composition that may be translucent when combined in solution. For the reasons stated above with respect to claim 1, there is also no motivation from the cited references for composition of claim 14.

For the above-stated reasons, claim 14 is not obvious over the cited references. Claims 15-23 depend from claim 14 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 14, claims 15-23 are not obvious over the cited references.

Applicants respectfully request that the rejection under 35 U.S.C. §103(a) be withdrawn.

G. Double Patenting

The Patent Office rejects claims 1-23 under the judicially created doctrine of obviousness-type double patenting over U.S. patent application Serial No. 09/365,156. Applicants submit herewith a terminal disclaimer disclaiming the term of any patent granted on the Application to the term of the patent granted on application Serial No. 09/365,156. Applicants respectfully request that the Patent Office withdraw the double patenting rejection to claims 1-23.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendments. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Date: 9/27/02

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on September 27, 2002.

Nedy Calderon 9/27/02

Nedy Calderon Date

ATTACHMENT: VERSION WITH MARKINGS TO SHOW CHANGES MADE.

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Please amend the Specification as follows:

[0025] In one embodiment, the composition as a beverage includes a stabilizing agent to facilitate the solubilization of the individual components in solution. The stabilizing agent is one or more of a maltol commercially available from Cultor Food Science, Inc. of Ardsley, New York. ~~A;~~ a composition of carrageenan and maltodextrin such as sold under the trademark INSTA*THICK C-15L™ by Zumbro Inc. of Hayfield, Minnesota, ~~;~~ or a xanthan gum such as sold under the trademark KELTROL™, by NutraSweet Kelco Company of Deerfield, Illinois. Preferably, a composition is combined with a combination of maltol and a composition of carrageenan and maltodextrin or a composition of maltol and xanthan gum(s). In this manner, the solubility of the individual components of the composition, particularly soy isoflavones, is improved. A suitable range of maltol in a beverage composition is 0.1 g to 0.4 g for a 240 mL composition. In a composition such as described including soy isoflavones, the level of 0.1 g in 240 mL aqueous solution was found to increase the solubility of individual components including the soy isoflavones in aqueous solution. A suitable range of a composition of carrageenan and maltodextrin commercially available under the trademark INSTA*THICK is 1.0 g to 4.0 g for a 240 mL composition. The level of 1 g in 240 mL water was found to increase the solubility of the components in aqueous solution. A suitable range of xanthan gum commercially available under the trademark KELTROL-T is 0.024 g to 0.096 g for a 240 mL composition. The level of 0.024 g in 240 mL aqueous solution generally does not create a viscous mouthfeel. The 0.096 usage level is used in the preparation of 4x concentrated syrup.

IN THE CLAIMS

Please amend the following claims:

1. (Amended) A method comprising:

administering a beverage composition suitable for human consumption comprising effective amounts of the following solubilized components:

a calcium compound;

~~an~~ a pH modifying organic acid in an amount up to the equivalent amount of a calcium of the calcium compound; and

inulin,

wherein the effective amounts are sufficient to reduce the risk of bone density loss.

3. (Amended) The method of claim 2, wherein the beverage composition further ~~comprising~~comprises:

a stabilizing agent comprising maltol and one of carrageenan and maltodextrin and a xanthan gum~~, the stabilizing agent present in an amount such that the solubility of the soy isoflavone in the beverage is greater than 75 percent~~.

7. (Amended) A method comprising:

administering a beverage composition suitable for human consumption comprising amounts of the following solubilized compounds:

a calcium compound;

a magnesium compound;

~~an~~ a pH modifying organic acid in an amount up to the equivalent amount of a calcium of the calcium compound; and

a fructo-oligosaccharide.

9. (Amended) The method of claim 7, wherein the beverage composition further ~~comprising~~comprises:

a stabilizing agent comprising maltol and one of carrageenan and maltodextrin and a xanthan gum~~, the stabilizing agent present in an amount such that the solubility of the soy isoflavone in the beverage is greater than about 75 percent~~.

14. (Amended) A composition suitable for human consumption comprising a portion of a daily amount of:

a dietary acceptable calcium compound;

a dietary acceptable magnesium compound;

a dietary acceptable inulin; and

an acidifier in an amount up to the equivalent amount of a calcium of the calcium compound~~.~~,

wherein, when combined in a solution, the composition can be translucent.

16. (Amended) The composition of claim 15, wherein the composition is one of a ready-to-drink solubilized beverage and a soluble beverage preparation.

18. (Amended) The composition of claim 17, further comprising a dietary acceptable isoflavone ~~wherein the solubility of the isoflavone is greater than 75 percent~~.

23. (Amended) The composition of claim 14, wherein the magnesium compound further comprises phosphorus.